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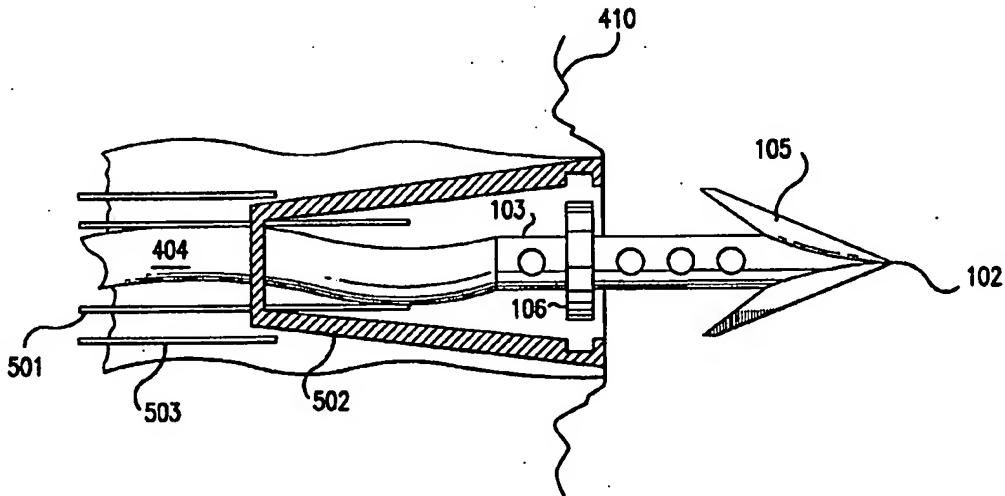


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(21) International Application Number: PCT/US98/22835 (22) International Filing Date: 29 October 1998 (29.10.98) (30) Priority Data: 08/968,131 12 November 1997 (12.11.97) US (71) Applicant (<i>for all designated States except US</i>): BOSTON SCIENTIFIC CORPORATION [US/US] ; One Boston Scientific Place, Natick, MA 01760 (US). (72) Inventor; and (75) Inventor/Applicant (<i>for US only</i>): ADAMS, Ronald, D. [US/US]; 18 Hillside Drive, Holliston, MA 01746-1480 (US). (74) Agents: BRAINARD, Charles, R. et al.; Kenyon & Kenyon, 1025 Connecticut Avenue, N.W., Washington, DC 20036 (US).	(81) Designated States: AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, US, UZ, VN, YU, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG). Published <i>With international search report.</i>
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(54) Title: GASTROINTESTINAL COMPRESSION CLIPS



(57) Abstract

Medical devices and methods used to cause hemostasis of blood vessels located along the gastrointestinal tract. The medical devices include a clip having a stem, an anchor at a first end of the stem and a bolster at or near a second end of the stem. Methods of deploying the medical devices are disclosed.

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GASTROINTESTINAL COMPRESSION CLIPS**Field of the Invention**

The present invention relates to compression
5 clips, and more specifically, to compression clips used
to cause hemostasis of blood vessels located along the
gastrointestinal tract.

Background of the Invention

10 Gastrointestinal ("GI") bleeding is often
associated with peptic ulcer disease and can be fatal if
not treated immediately. For the estimated patient
population of 10,000, approximately 2,000 will die during
management of GI bleeding. This problem has prompted the
15 development of a number of endoscopic therapeutic
approaches to achieve hemostasis, such as the injection
of sclerosing agents and contact thermo-coagulation
techniques. Although such approaches are often
effective, bleeding continues for many patients and
20 emergency corrective surgery therefore becomes necessary.
Because surgery is an invasive technique that is
associated with many undesirable side effects, there
exists the need for highly effective, less invasive
procedures.

25 Mechanical hemostatic devices are used in
various parts of the body, including GI applications.
Such devices are typically in the form of clamps, clips,
staples, sutures, etc., which are able to apply
sufficient constrictive forces to blood vessels so as to
30 limit or interrupt blood flow. One of the problems
associated with conventional hemostatic devices, however,
is that they are delivered using rigid-shafted
instruments via incision or trocar cannula. Moreover,

conventional endoscopic hemostatic devices are not generally strong enough to consistently control GI bleeding.

5 Summary of the Invention

The present invention provides medical devices and methods of deploying such medical devices for causing the hemostasis of blood vessels located along the gastrointestinal tract. Each of the medical devices of 10 the present invention comprises a clip that includes a stem having a first end and a second end; an anchor at the first end of the stem; and a bolster at or near the second end of the stem. In one embodiment of the invention, the stem has at least one transverse hole 15 therein, and the bolster is slidable about the stem and includes a flap adapted to be inserted into the transverse hole. In a second embodiment of the invention, the stem has at least one engaging member extending therefrom, and the bolster has a central 20 opening that is wider than the stem at a location where the engaging member is absent but is more narrow than the stem at a location where the engaging member is present. In a third embodiment of the invention, the stem has at least one dimple therein and the bolster has at least one 25 locking element attached thereto by a spring, wherein the locking element fits within the dimple. In a fourth embodiment of the invention, the bolster is fixed at the second end of the stem.

One advantage of the present invention is that 30 it provides a medical device that, when deployed, creates sufficient tissue compression to hemostatically control GI bleeding.

Another advantage of the present invention is that it provides a consistent, reproducible means for 35 controlling GI bleeding.

Another advantage of the present invention is that it provides a definitive solution to the problem of

GI bleeding.

Yet another advantage of the present invention is that it provides a means to control GI bleeding without resorting to open or laparoscopic surgical 5 techniques.

Brief Description of the Drawings

Fig. 1 illustrates a first embodiment of the medical device of the present invention.

10 Fig. 2 illustrates a second embodiment of the medical device of the present invention.

Figs. 3A-3B illustrate a third embodiment of the medical device of the present invention.

15 Fig. 4 illustrates a fourth embodiment of the medical device of the present invention.

Fig. 5A shows an end view of an example of a delivery device, in accordance with the present invention.

20 Figs. 5B-5E illustrate a method of deploying a medical device having a moveable bolster, in accordance with the present invention.

Figs. 6A-6C illustrate an alternative method of 25 deploying a medical device in accordance with the present invention.

Figs. 7A-7C illustrate a method of deploying a medical device having a fixed bolster, in accordance with the present invention.

Detailed Description

30 The present invention provides medical devices and methods of deploying such medical devices for causing the hemostasis of blood vessels located along the gastrointestinal tract. The medical devices each comprise a clip comprising a stem having a first end and 35 a second end, an anchor at the first end of the stem, and a bolster. The bolster is herein disclosed to be "at or near" the second end of the stem in that the bolster is

either fixed at the second end of the stem, or positioned at a location between the second and first ends of the stem.

In a first embodiment of the invention as shown 5 in Fig. 1, medical device 100 includes a stem 101 having first end 102 and second end 103. Stem 101 has at least one transverse hole 104 therein of any suitable shape (e.g. circular, rectangular, square, etc.). Stem 101 is further characterized by an anchor 105 at its first end 10 102. Anchor 105 comprises at least one anchor member that extends away from stem 101 and towards second end 103. Medical device 100 also comprises a bolster 106, which includes a flap 107 adapted to be inserted into hole 104.

The medical devices of the present invention 15 are made from any suitable biocompatible polymeric or metallic material. It is preferred, however, that stem 101 be made from an elastic material such as stainless steel, nitinol, or any suitable polymeric material such as polyethylene. The elasticity of stem 101 permits 20 anchor 105 to be compressed to facilitate delivery within a body lumen. It is also preferred, although not necessary, that bolster 106 be made from the same material as stem 101. Bolster 106 is made from a material, however, that is rigid enough so that, when in 25 use, flap 107 remains in a selected hole 104 to apply pressure against a GI wall. Flap 107 is optionally attached to bolster 106 by a "one-way" hinge or a similar mechanism that allows bolster to be moved towards first 30 end 102 but prevents movement towards second end 103 once flap 107 is inserted into a desired hole 104.

In a second embodiment of the invention, stem 101 of medical device 200 has at least one engaging member 120 extending therefrom as shown in Fig. 2. Where multiple engaging members 120 are used, they are arranged 35 in any suitable configuration, such as the series of engaging member pairs shown in Fig. 2. In this embodiment, bolster 106 has a central opening that is

wider than the stem at a location where engaging member 120 is absent but is more narrow than the stem at a location where engaging member 120 is present.

The materials used for stem 101 and bolster 106 of medical device 200 are selected to facilitate the movement of bolster 106 over engaging members 120 until bolster 106 is positioned at a desired location along stem 101. For example, bolster 106 is elastically deformable enough to be pushed over engaging members 120 without plastically deforming, or alternatively, engaging members 120 are elastically deformable enough so as to allow the passage of bolster 106 towards first end 102 of stem 101 without causing the plastic deformation of engaging members 120.

In a third embodiment of the invention, stem 101 of medical device 300 includes at least one dimple 305, as shown in Fig. 3A. Where multiple dimples are used, they are arranged in any suitable configuration such as the series of dimple pairs shown in Fig. 3A. Alternatively, dimples 305 are annular cavities around the circumference of stem 101. Bolster 106 includes locking elements 307, such as spheres, that are attached to bolster 106 by springs 306, as shown in Fig. 3B. Springs 306 are of any suitable configuration, although they are shown as coils in Fig. 3B. Locking elements 307 fit within dimples 305 for placing bolster 106 at a desired location along stem 101. Springs 306 are of sufficient strength to keep locking elements 307 within dimples 305 when medical device 300 is in use. Springs 306 and locking elements 307 are made from any suitable material, such as, for example, steel or nitinol.

In a fourth embodiment of the invention, medical device 350 comprises a bolster 106 that is fixed to stem 101, as shown in Fig. 4. Bolster 106 is an integral part of device 350 or is rigidly attached to stem 101, for example. Like the embodiment shown in Figs. 1 and 2, it is preferred that stem 101 of device

350 be made from an elastic material to facilitate delivery within a body lumen.

The deployment of medical device 100 to a location along the GI tract is accomplished by any 5 suitable means. For example, deployment of device 100 is accomplished with the use of delivery device 400 as shown in Figs. 5A - 5E. Delivery device 400 comprises an endoscope 401 having an outer sheath 402 for containing at least one delivery tube 403. Endoscope 401 is 10 preferably orally inserted into the GI tract, although it is also able to be inserted rectally. "Endoscope" as used herein is intended to include similar instrumentation such as a gastroscope or duodenoscope. Endoscope 401 is typically about 10mm in diameter, and the maximum 15 diameter for outer sheath 402 is typically about 20mm. Delivery tube 403 houses medical device 100 such that anchor 105 is contained by sleeve 403 in a compressed or "folded" configuration, as shown in Fig. 5B.

When a target location along the GI tract is 20 identified by endoscope 401, the end of delivery device 400 is positioned against or adjacent to the GI wall 410. Stem 101 is pushed out of sleeve 403 by stem pusher 404 such that the first end 102 of stem 101 pierces the GI wall 410, as shown in Fig. 5C. Once stem 101 is extended 25 to a desired depth within GI wall 410, bolster pusher 406 is used to push bolster 106 over stem 101 and towards first end 102. As bolster 106 proceeds towards first end 102, an increasing pressure is applied to the tissue between GI wall 410 and anchor 105. Anchor 105 is thus 30 urged back towards GI wall 410, resulting in the expansion of anchor 105 to its "unfolded" configuration and thus locking stem 101 in its position as shown in Fig. 5D. When sufficient pressure is applied to the GI wall 111 to cause hemostasis of an adjacent bleeding 35 blood vessel, flap 107 of bolster 106 is locked into the at least one transverse hole 104 in stem 101. As such, bolster 106 maintains pressure of the GI tissue and

permanently induces hemostasis of the adjacent blood vessels. Medical device 100 is shown in its deployed configuration in Fig. 5E.

Medical devices 200 and 300 are deployed, for example, via the method described and shown for medical device 100. Although bolster 106 is slidable over stem 101 for each of devices 200 and 300, the force exerted by the GI wall 410 on bolster 106 after deployment is not great enough to move bolster 106 back towards second end 103 of stem 101.

As an alternative example, medical devices 100, 200 and 300 are deployed as shown in Figs. 6A-6C. For example, the anchor of medical device 100 is held in a compressed configuration by compression sheath 501. Bolster 106 is disposed about compression sheath 501 and its position is controlled by the movement of clip 502 when bolster 106 is engaged by clip 502. The first end 102 of stem 101 is used to pierce GI wall 410 while the anchor members of anchor 105 are held in a compressed configuration, as shown in Fig. 6B. After stem 101 has been inserted to a desired depth within GI wall 410, compression sheath 501 is retracted to allow the anchor members of anchor 105 to expand to an unfolded configuration, as shown in Fig. 6C. Clip 502 is advanced by a pusher bar or the like such that bolster 106 is moved over stem 101 until a desired pressure is applied to GI wall 410. Locking collar 503 is then retracted, allowing clip 502 to disengage bolster 106, as shown in Fig. 6C. Medical device 100 thus deployed is shown in Fig. 5E.

Medical device 350, having a bolster that is fixed to its stem, is deployed with the use of delivery device 400, for example. In the case of device 350, however, multiple pusher bars are not necessary and the device is loaded into delivery tube 403 as shown in Fig. 7A. Device 350 is pushed out of sleeve 403 by device pusher bar 404 such that the first end 102 of stem 101

pierces the GI wall 410, as shown in Fig. 7B. Once stem 101 is extended to a desired depth within GI wall 410, which is typically the entire length of stem 101, device 350 is released from pusher bar 404. Because of the pressure in the tissue between GI wall 410 and first end 102 of stem 101, anchor 105 is urged back towards GI wall 410, thus resulting in the expansion of anchor 105 to its "unfolded" configuration. Device 350 is thus locked in its position as shown in Fig. 7C.

10 The medical devices of the present invention are of any suitable size, although it is preferred that stem 101 be about 0.5-2 cm, preferably about 1 cm in length, and about 0.5-5 mm, preferably about 2 mm in diameter.

15 The medical devices of the present invention are preferably located within about 1 cm from any bleeding blood vessel. When used to stop bleeding from an ulcer bed, the medical devices of the present invention are located within about 5 mm, preferably about 2 mm, and more preferably about 1 mm from the edge of an ulcer bed. As many as six or more of the medical devices of the present invention are used to surround an ulcer bed to stop the bleeding thereof.

20 The present invention provides a reliable, definitive treatment for the problem of gastrointestinal bleeding. When deployed in accordance with the present invention, the clips provide sufficient strength to produce permanent hemostasis.

25 It will be obvious to those skilled in the art, having regard to this disclosure, that other variations on this invention beyond those specifically exemplified here may be made. Such variations are, however, to be considered as coming within the scope of this invention as limited solely by the following claims.

What is claimed is:

- 1 1. A medical device for causing the hemostasis of a
2 blood vessel located along the gastrointestinal
3 tract, said medical device comprising:
 - 4 a clip comprising a stem having a first end and
5 a second end;
 - 6 an anchor at the first end of said stem; and
 - 7 a bolster at or near the second end of said
8 stem.
- 1 2. The medical device of claim 1, wherein said anchor
2 comprises at least one anchor member extending away
3 from said stem of said clip and towards the second
4 end of said stem.
- 1 3. The medical device of claim 1, wherein said medical
2 device comprises stainless steel.
- 1 4. The medical device of claim 1, wherein said medical
2 device comprises nitinol.
- 1 5. The medical device of claim 1, wherein said medical
2 device comprises a polymeric material.
- 1 6. The medical device of claim 1, wherein said bolster
2 is an integral part of said stem.
- 1 7. The medical device of claim 1, wherein said bolster
2 is slidable about said stem.
- 1 8. The medical device of claim 7, wherein:
 - 2 said stem of said clip has at least one

3 transverse hole therein; and

4 said bolster comprises:

5 a central opening, wherein said central
6 opening is wider than said stem of said
7 clip; and

8 a flap adapted to be inserted into said
9 hole in said stem.

1 9. The medical device of claim 7, wherein:

2 said stem of said clip has at least one
3 engaging member extending therefrom; and

4 said bolster comprises a central opening,
5 wherein said central opening is wider than said
6 stem in a location where said at least one
7 engaging member is absent and said central
8 opening is more narrow than said stem in a
9 location where said at least one engaging
10 member is present.

1 10. The medical device of claim 7, wherein:

2 said stem of said clip has at least one dimple
3 therein; and

4 said bolster comprises:

5 a central opening, wherein said central
6 opening is wider than said stem of said
7 clip; and

8 a locking element attached to said
9 bolster, wherein said locking element fits

10 into said dimple.

1 11. The medical device of claim 10, wherein:
2 said locking element is a sphere; and
3 said sphere is attached to said bolster by a
4 spring.

1 12. The medical device of claim 1, wherein said stem is
2 approximately 0.5-2 centimeters in length.

1 13. The medical device of claim 1, wherein said stem is
2 approximately 0.5-5 millimeters in diameter.

1 14. A method for causing the hemostasis of a blood
2 vessel located along the gastrointestinal tract,
3 said method comprising the steps of:

4 providing a clip, said clip comprising
5
6 a stem having a first end and a second
7 end, an anchor at the first end of said
8 stem, and
9 a bolster at or near the second end of
10 said stem;

11 delivering said clip to a target location along
12 the gastrointestinal tract; and

13 inserting said clip into the gastrointestinal
14 wall at said target location.

1 15. The method of claim 14, wherein said bolster is an
2 integral part of said stem.

1 16. The method of claim 14, wherein said bolster is
2 slidable about said stem.

1 17. The method of claim 16, wherein:

2 said stem of said clip has a transverse hole
3 therein;

4 said bolster comprises:

5 a central opening, wherein said central
6 opening is wider than said stem of said
7 clip; and

8 a flap adapted to be inserted into said
9 hole in said stem.

1 18. The method of claim 17, further comprising the steps
2 of sliding said bolster over said stem and towards
3 said first end of said stem; and inserting said flap
4 into said hole.

1 19. The method of claim 16, wherein:

2 said stem of said clip has at least one
3 engaging member extending therefrom; and

4 said bolster comprises a central opening,
5 wherein said central opening is wider than said
6 stem in a location where said at least one
7 engaging member is absent and said central
8 opening is more narrow than said stem in a
9 location where said at least one engaging
10 member is present.

1 20. The method of claim 19, further comprising the step
2 of sliding said bolster over said stem and towards
3 said first end of said stem.

1 21. The method of claim 16, wherein:

2 said stem of said clip has a dimple therein;

3 said bolster comprises:

4 a central opening, wherein said central
5 opening is wider than said stem of said
6 clip; and

7 a locking element attached to said
8 bolster, wherein said locking element fits
9 into said dimple.

1 22. The method of claim 21, further comprising the step
2 of sliding said bolster over said stem and towards
3 said first end of said stem such that said locking
4 element is placed in said dimple.

1 23. The method of claim 14, wherein said step of
2 delivering occurs via a natural body orifice.

1 24. The method of claim 23, wherein said natural body
2 orifice is a mouth.

1 25. The method of claim 14, wherein said target location
2 is within about 1 centimeter of the blood vessel.

1 26. A system to achieve the hemostasis of a blood vessel
2 located along the gastrointestinal tract, said
3 system comprising:

4 a clip, said clip comprising
5 a stem having a first end and a second
6 end,
7 an anchor at the first end of said stem,
8 and
9 a bolster at or near the second end of
10 said stem,

11 wherein said clip is configured to
12 apply pressure to tissue located along the
13 gastrointestinal tract to cause hemostasis
14 of said blood vessel; and

15 a delivery device.

1 27. The system of claim 26, wherein said delivery device
2 comprises:

3 an endoscope;

4 a delivery tube adjacent to said endoscope; and

5 a medical device in said delivery tube, said
6 medical device comprising

7 a clip comprising a stem having a first
8 end and a second end;
9 an anchor at the first end of said stem;
10 and
11 a bolster at or near the second end of
12 said stem.

1 28. The system of claim 27, further comprising an outer
2 sheath surrounding said endoscope.

1 29. The system of claim 28, wherein said delivery tube
2 is positioned between said endoscope and said outer
3 sheath.

1/13

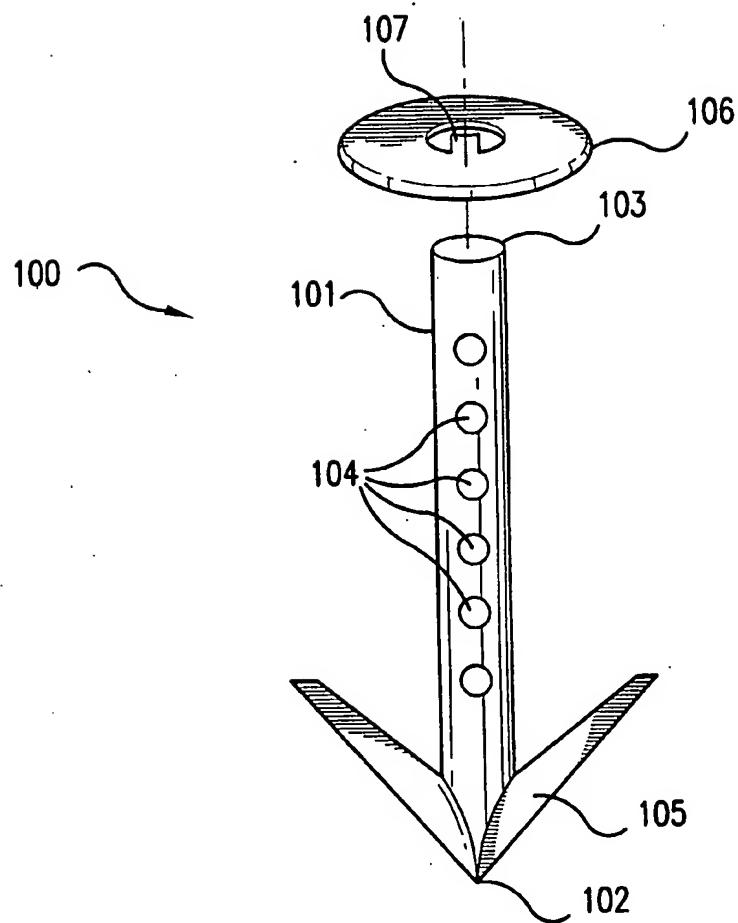


FIG.1

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2/13

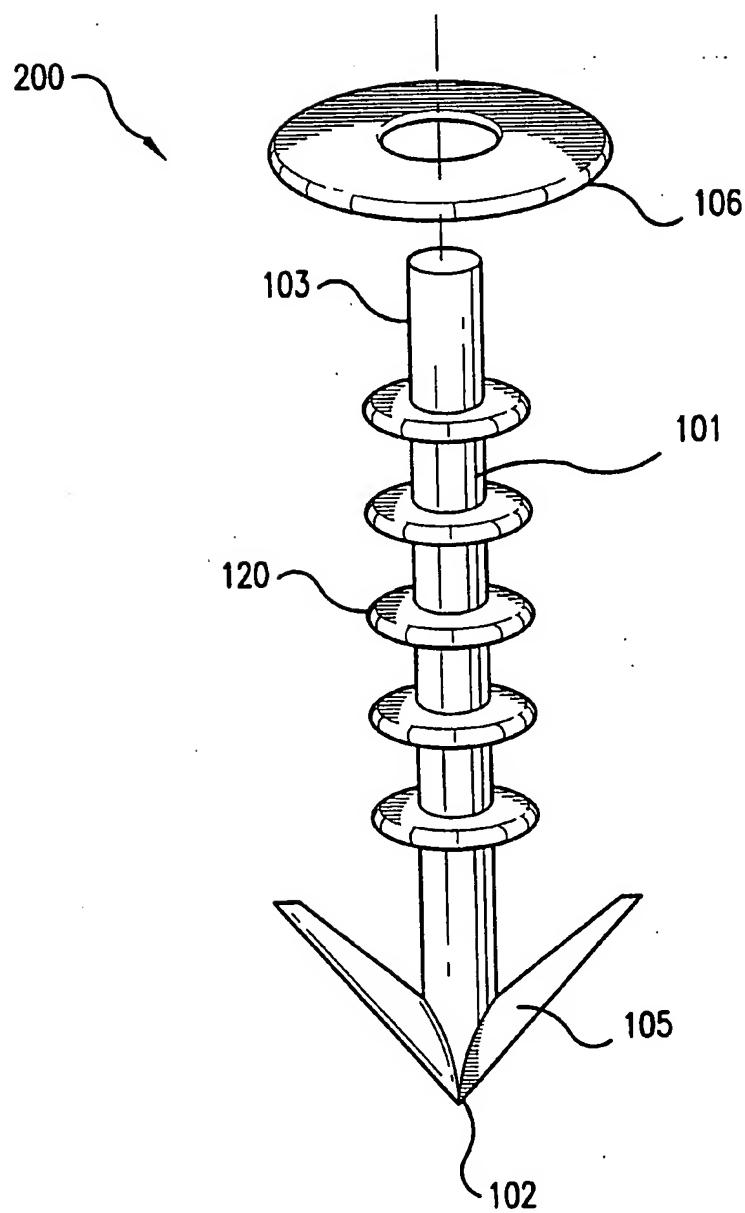


FIG.2

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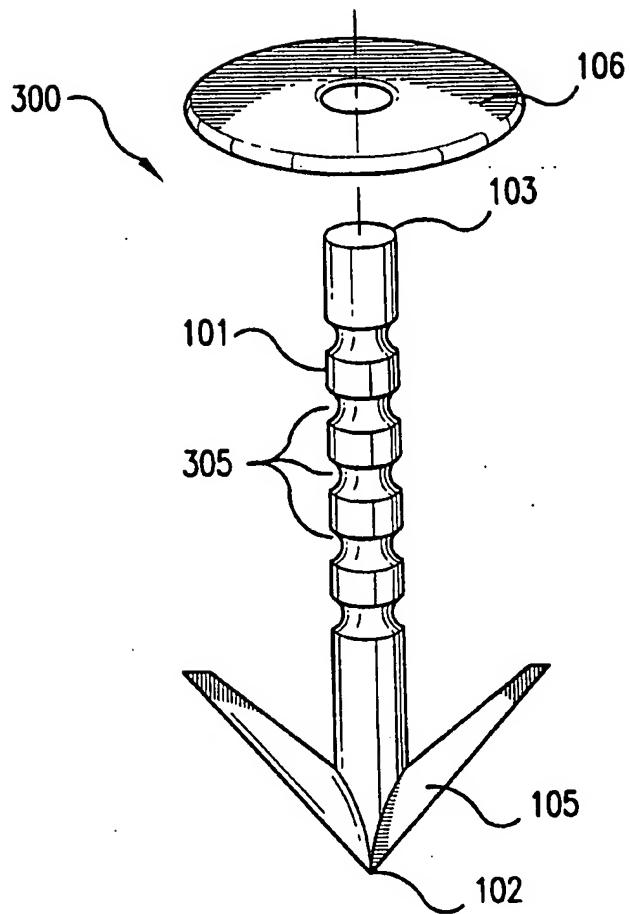


FIG.3A

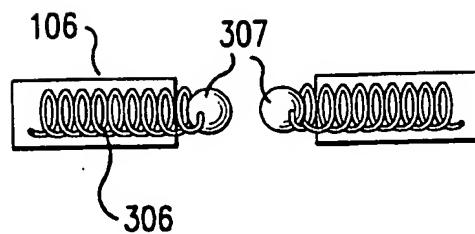


FIG.3B

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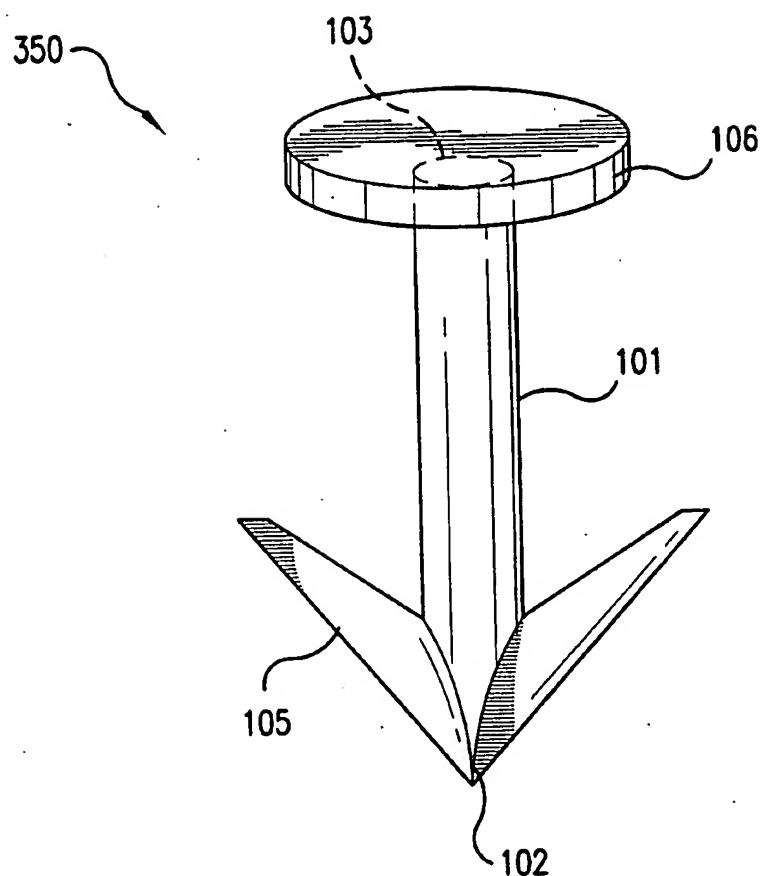


FIG.4

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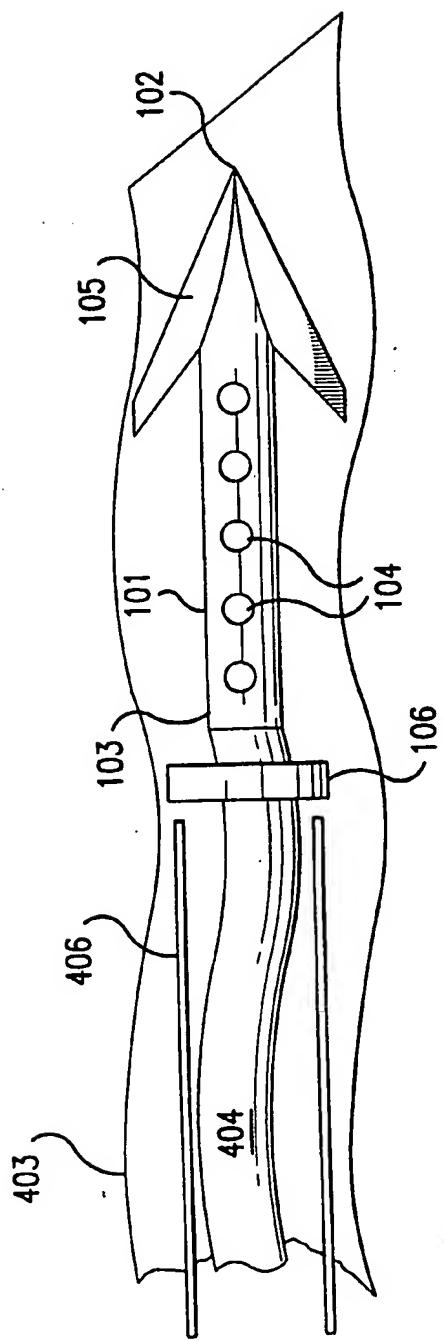


FIG. 5B

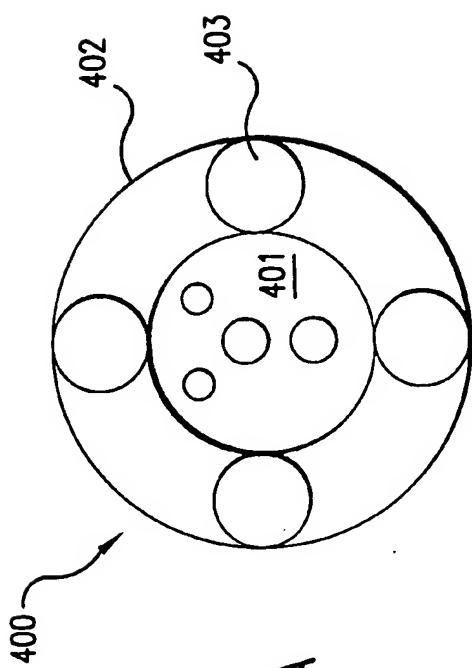


FIG. 5A

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6/13

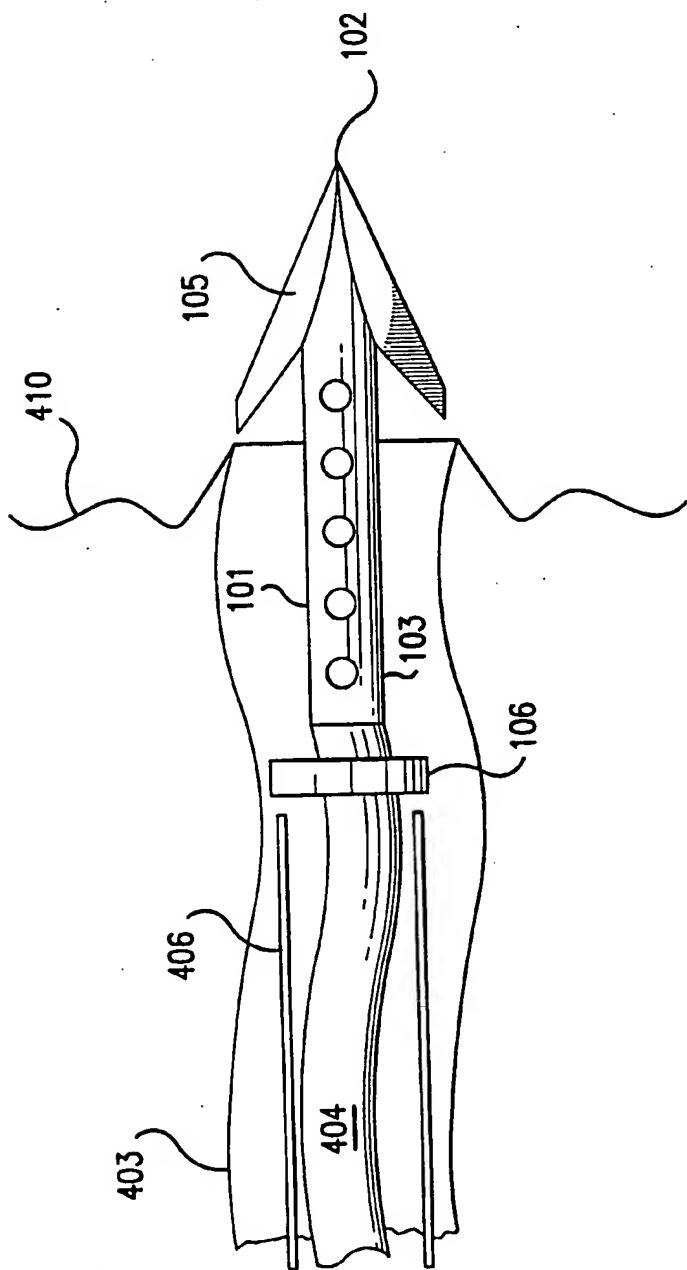


FIG. 5C

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7/13

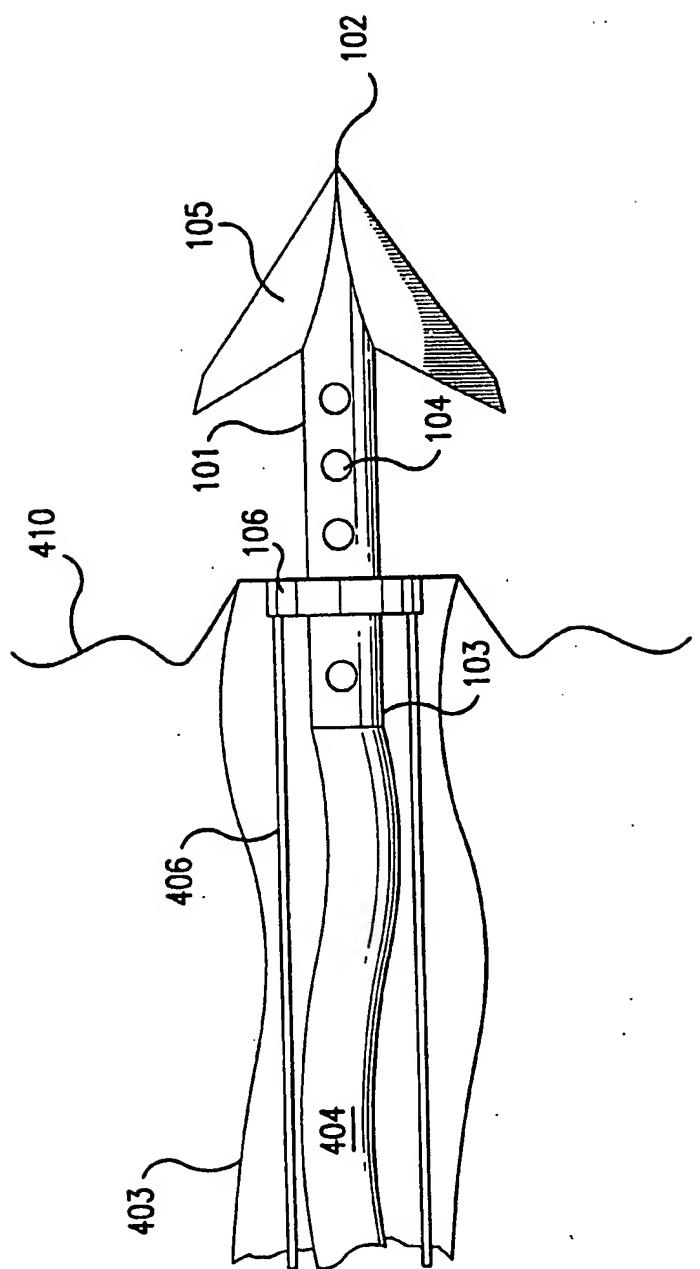


FIG. 5D

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8/13

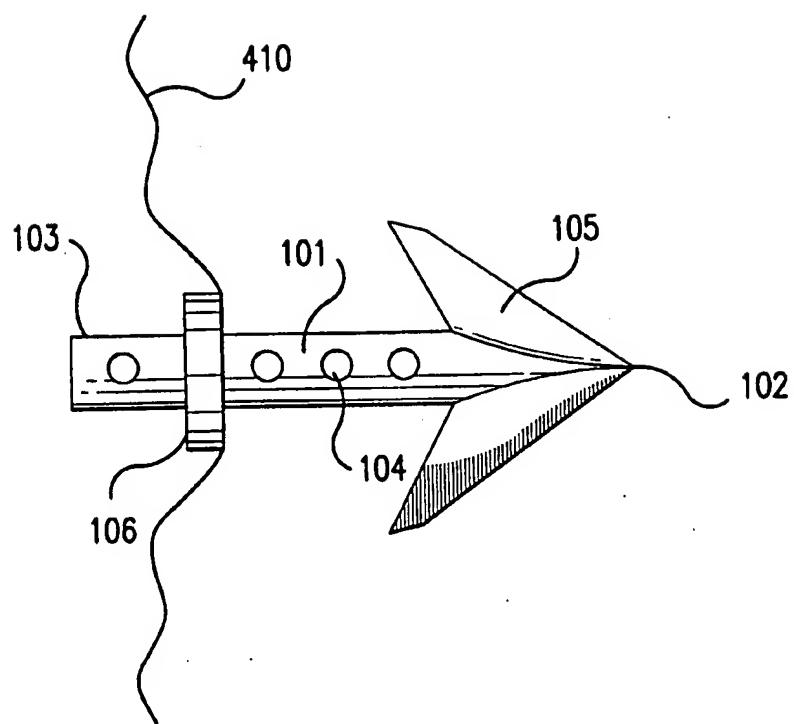


FIG.5E

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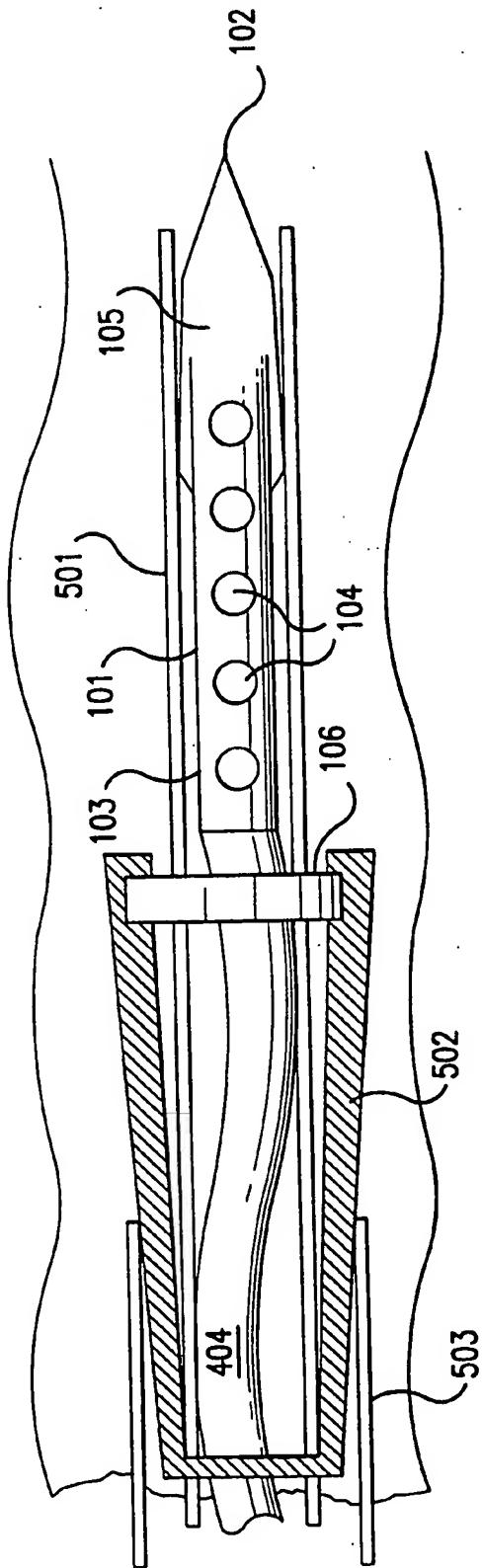


FIG. 6A

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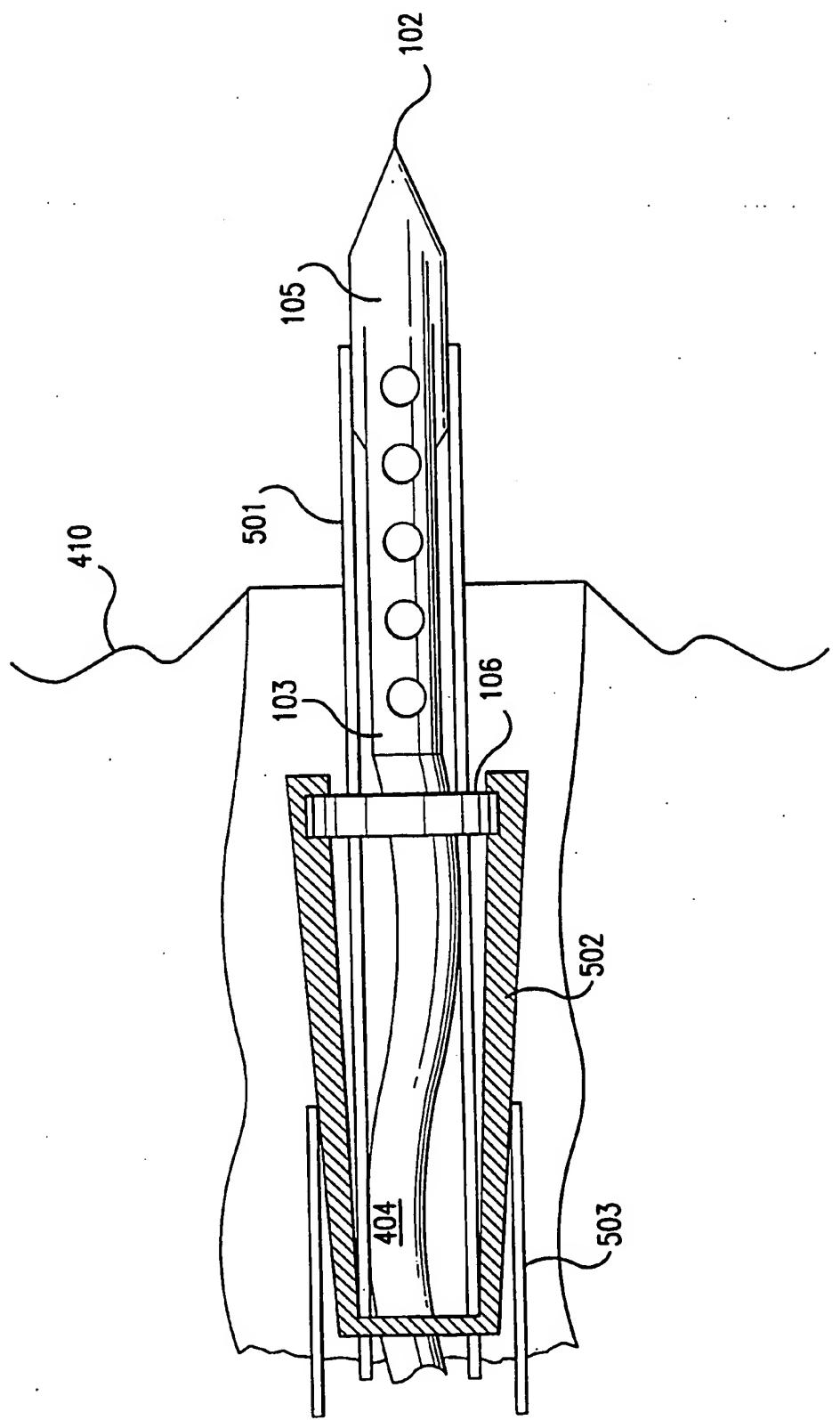


FIG. 6B

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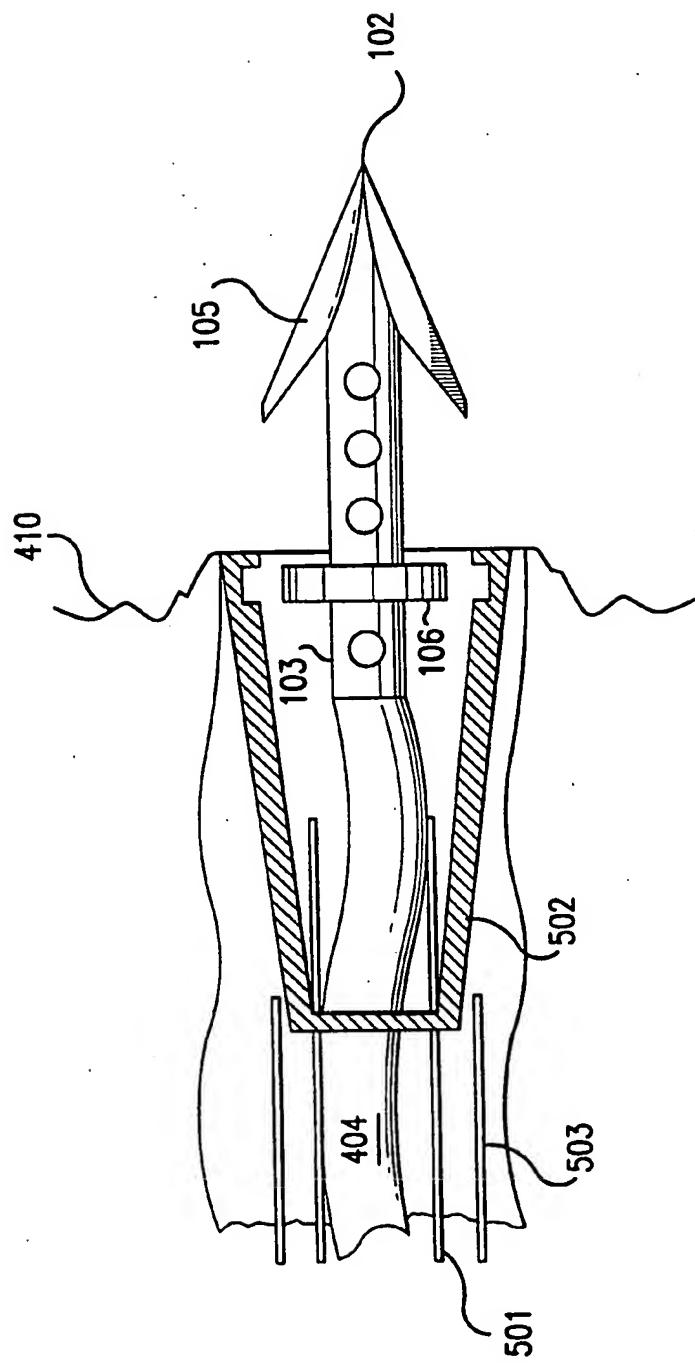


FIG. 6C

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12/13

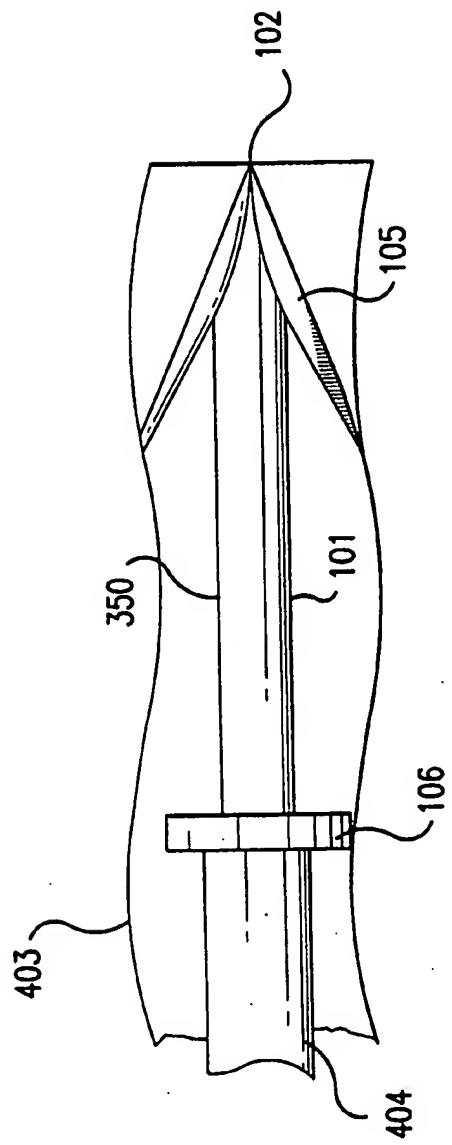


FIG.7A

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13/13

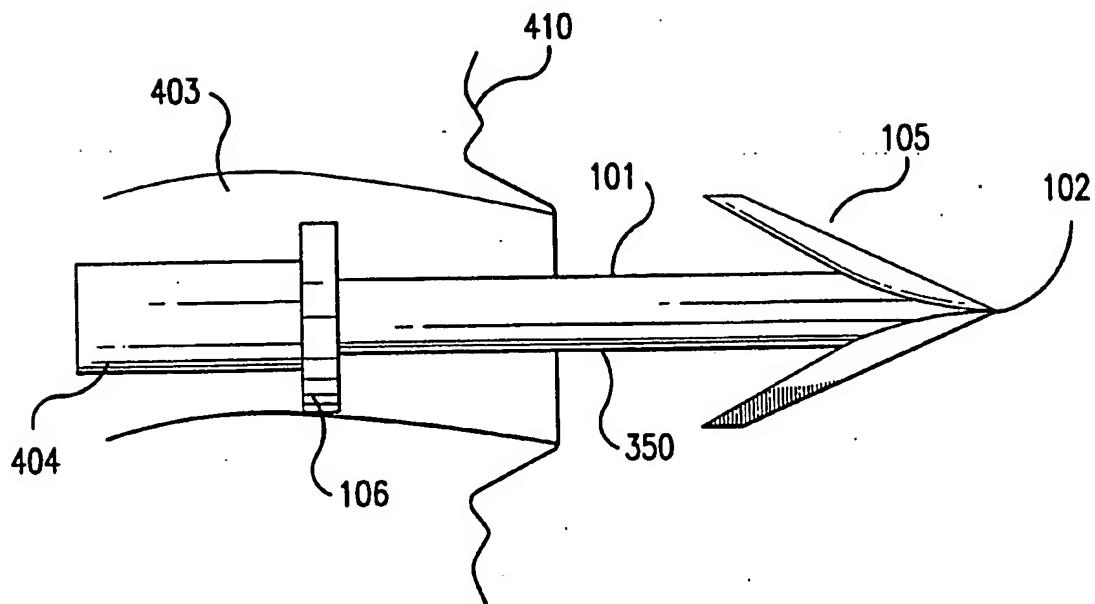


FIG. 7B

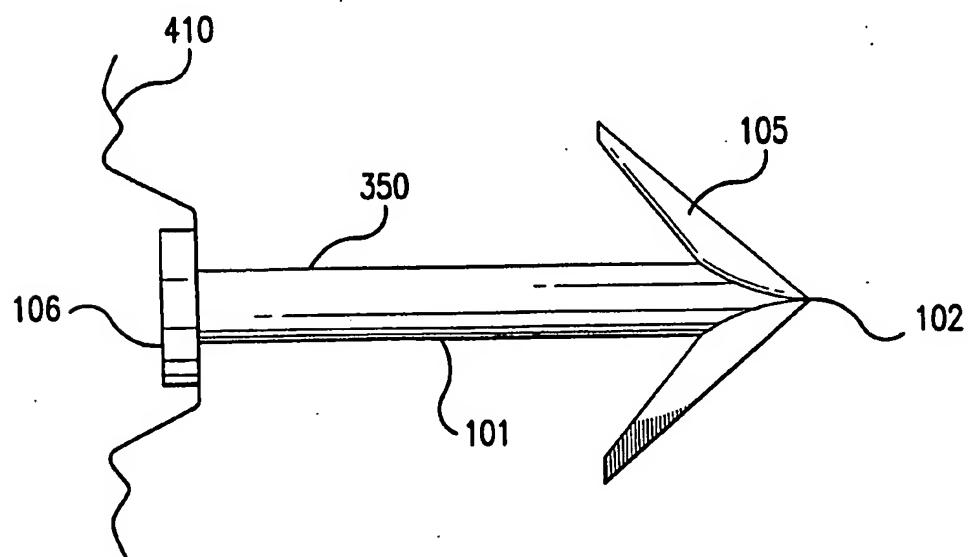


FIG. 7C

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INTERNATIONAL SEARCH REPORT

International Application No

PCT/US 98/22835

A. CLASSIFICATION OF SUBJECT MATTER
 IPC 6 A61B17/064 A61B17/122 A61B17/12

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
 IPC 6 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 464 421 A (WORTRICH) 7 November 1995 see column 3, last paragraph see column 1, paragraph 2; figure 2 ---	1,3-6, 12,13,26
X	US 5 203 864 A (PHILLIPS) 20 April 1993 see figures 1,9,14-17 ---	1-6,12, 13,26
X	US 5 423 858 A (USSC) 13 June 1995 see figures 1,2 ---	1,2,5,7, 9,10,12, 13,26
X	EP 0 632 999 A (USSC) 11 January 1995 see figures 2-4 ---	1,2,5,7, 12,13 8,9
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Patent family members are listed in annex.

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- *O* document referring to an oral disclosure, use, exhibition or other means
- *P* document published prior to the International filing date but later than the priority date claimed

T later document published after the International filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

X document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

Y document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

& document member of the same patent family

Date of the actual completion of the international search

4 February 1999

Date of mailing of the international search report

11/02/1999

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl.
Fax: (+31-70) 340-3016

Authorized officer

Barton, S

INTERNATIONAL SEARCH REPORT

International Application No

PCT/US 98/22835

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5 395 391 A (ESSIG) 7 March 1995 see figure 5 ---	8
A	GB 1 560 282 A (KNEPSHIELD) 6 February 1980 see the whole document ---	27
A	DE 20 46 011 A (THOMAS & BETTS) 15 April 1971 ----	
A	US 4 534 350 A (GOLDEN) 13 August 1985 -----	

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 98/22835

Box I Observations where certain claims were found unsearchable (Continuation of Item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. Claims Nos.: because they relate to subject matter not required to be searched by this Authority, namely:

2. Claims Nos.: because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

3. Claims Nos.: because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking(Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

The additional search fees were accompanied by the applicant's protest.
 No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/US 98/22835

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